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SYNGENTA BIOTECHNOLOGY, INC.
PATENT DEPARTMENT
3054 CORNWALLIS ROAD
P.O. BOX 12257
RESEARCH TRIANGLE PARK, NC 27709-2257

EXAMINER

KUBELIK, ANNE R

ART UNIT PAPER NUMBER

1638

DATE MAILED: 03/25/2003

16

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/901,737

Applicant(s)

LEBEL ET AL.

Examiner

Anne R. Kubelik

Art Unit

1638

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 20 December 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) 6-9, 12-23 and 30 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 6-9, 12-23 and 30 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s) _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

Art Unit: 1638

DETAILED ACTION

1. The amendments to the specification, the amendments to claims 6-7, 9, 12-15, 18-20 and 22-23, the cancellation of claims 11 and 24-29, and the addition of claim 30, requested in Paper No. 14, filed 20 December 2002, have been entered. Claims 6-9, 12-23 and 30 are pending.

2.

3. The drawings are objected to for the reasons indicated on the accompanying form PTO 948. Corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance. See 37 CFR 1.85(a) and MPEP 608.02(b).

4. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Response to Amendment

5. The rejection of claims 6, 11, 18 and 21-22 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter is WITHDRAWN in light of amendment to the claims.

6. The rejection of claims 6, 11, 18 and 21-22 are rejected under 35 U.S.C. 102(b) as being anticipated by Lashbrook et al (1994, Plant Cell 6:1485-1493) is WITHDRAWN in light of amendment to the claims.

7. The rejection of claims 6-9 and 11-23 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject

Art Unit: 1638

matter that Applicant regards as the invention is WITHDRAWN in light of amendment to the claims.

Claim Objections

8. Claim 16 is objected to because "derives" should be --is derived--.

Claim Rejections - 35 USC § 112

9. Claims 6-9, 12-14, 16-23 and 30 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The rejection is repeated for the reasons of record as set forth in the Office action mailed 20 June 2002, as applied to claims 6-9, 11-14 and 16-23. Applicant's arguments filed 20 December 2002 have been fully considered but they are not persuasive.

Applicant urges that the specification adequately describes the claimed invention and that a description of all other DNA molecules encoding cellulases is not required; teaching the *T. fusca* genes is enough. Applicant urges that reliance on *Eli Lilly* is misplaced because that only addresses what is required to describe a cDNA molecule, which is not claimed per se in the instant invention; additionally, nucleic acids encoding cellulases are well-known. Applicant urges that the cited paragraph from *Amgen* is directed to enablement, not written description (response pg 13-17).

Art Unit: 1638

This is not found persuasive. the specification does not describe nucleic acids encoding cellulases from *Thermomonospora species* other than *T. fusca*, and certainly does not describe a representative number of such nucleic acids from all organisms. Description of the nucleic acid is required to describe a plant transformed with the nucleic acid. Amgen means that a description of what a nucleic acid encodes does not describe the nucleic acid itself, and is thus directed to written description.

10. Claims 6-9, 12-14, 16-23 and 30 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for *T. fusca* β -1,4-endoglucanase-encoding sequences and plants transformed with them, does not reasonably provide enablement for nucleic acids encoding all cellulases, plants transformed with those cellulases, or non-transformed plants that express cellulases. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims. The rejection is repeated for the reasons of record as set forth in the Office action mailed 20 June 2002, as applied to claims 6-9, 11-14 and 16-23. Applicant's arguments filed 20 December 2002 have been fully considered but they are not persuasive.

Applicant urges that the specification on pg 4 and 14-15 teaches various cellulases that have been cloned; Applicant includes copies of the references on pg 15. Applicant urges that the specification provides a reasonable amount of guidance to express a cellulase in a plant, in the form of guidance regarding plant transformation vectors, methods, codon optimization and plant promoters, as well as the working examples A-C. Applicant urges that some experimentation is permitted (response pg 17-20).

Art Unit: 1638

This is not found persuasive because. Pg 4 of the specification teaches *T. fusca* cellulases. Collmer et al, Ghangas et al, Wilson, and Lao et al all teach *T. fusca* endocellulases. Only Thomas et al discusses cellulases from other organisms, and only addresses the enzymes themselves, not the nucleic acids encoding the enzymes. Thus, the specification does not teach nucleic acids encoding other cellulases and does not provide guidance for expressing other cellulases.

Claim Rejections - 35 USC § 102

11. Claims 6-7 and 17-23 remain rejected under 35 U.S.C. 102(b) as being anticipated by Yoshikawa et al (1993, Naturwissenschaften 80:417-420) in light of each of Takeuchi et al (1990, Plant Physiol. 93:673-682) and Melchers et al (1993, Plant Mol. Biol. 21:583-593). The rejection is repeated for the reasons of record as set forth in the Office action mailed 20 June 2002, as applied to claims 6-7, 11 and 17-23. Applicant's arguments filed 20 December 2002 have been fully considered but they are not persuasive.

Applicant urges that β -1,3-endoglucanase is not a cellulase, which is a class of enzymes that degrade cellulose by hydrolyzing β -1,4-linkages of cellulose (response pg 22-23).

This is not found persuasive because the specification on pg 3, lines 14-25, describes β -1,3-endoglucanase as a cellulose degrading enzyme and states that β -1,3-endoglucanases are also called endocellulases.

12. Claims 6-7, 12-13, 18 and 21 remain rejected under 35 U.S.C. 102(e) as being anticipated by Borriss et al (US Patent 5,470,725, filed February 1990). The rejection is repeated for the reasons of record as set forth in the Office action mailed 20 June 2002, as applied to claims 6-7,

Art Unit: 1638

11-13, 18 and 21. Applicant's arguments filed 20 December 2002 have been fully considered but they are not persuasive.

Applicant urges that Boriss does not describe a cellulase, but instead describes a (1,3-1,4)- β -glucanase, and urges that (1,3-1,4)- β -glucans are not components of cellulose (response pg 24-25).

This is not found persuasive because the specification on pg 3, lines 14-25, describes β -1,3-endoglucanase as a cellulose degrading enzyme and states that β -1,3-endoglucanases are also called endocellulases.

13. Claims 6-9, 12-13, 18-23 and 30 are rejected under 35 U.S.C. 102(e) as being anticipated by Ryals et al (US Patent 5,614,395, filed January 1993). The rejection is repeated for the reasons of record as set forth in the Office action mailed 20 June 2002, as applied to claims 6-9, 11-13 and 18-23. Applicant's arguments filed 20 December 2002 have been fully considered but they are not persuasive.

Applicant urges that β -(1,3)-endoglucanases are not cellulases (response pg 25).

This is not found persuasive because the specification on pg 3, lines 14-25, describes β -1,3-endoglucanase as a cellulose degrading enzyme and states that β -1,3-endoglucanases are also called endocellulases.

Claim Rejections - 35 USC § 103

14. Claims 6-8, 16-18 and 21-23 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Bennett et al (1992, US Patent 5,168,064). The rejection is repeated for the reasons of record as set forth in the Office action mailed 20 June 2002, as applied to claims 6-8,

Art Unit: 1638

11, 16-18 and 21-23. Applicant's arguments filed 20 December 2002 have been fully considered but they are not persuasive.

Applicant urges that β -1,3-endoglucanase is not a cellulase (response pg 26-27).

This is not found persuasive because the specification on pg 3, lines 14-25, describes β -1,3-endoglucanase as a cellulose degrading enzyme and states that β -1,3-endoglucanases are also called endocellulases.

15. Claims 6-7, 11-15 and 17-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yoshikawa et al (*supra*) in view of Lao et al (1991, J. Bacteriol. 173:3397-3407). The rejection is repeated for the reasons of record as set forth in the Office action mailed 20 June 2002, as applied to claims XXXXXXXXX. Applicant's arguments filed 20 December 2002 have been fully considered but they are not persuasive.

Applicant urges that β -1,3-endoglucanase is not a cellulase; thus, it would not be obvious to use a cellulase in the invention. Furthermore, Applicant urges that because the enzymatic activity of *T. fusca* endo- β -1,4-glucanase is different from the β -1,3-endoglucanase used by Yoshikawa, the plants would not be resistant to disease and would not be suitable for Yoshikawa's intended purpose (response pg 27-28).

This is not found persuasive because the specification on pg 3, lines 14-25, describes β -1,3-endoglucanase as a cellulose degrading enzyme and states that β -1,3-endoglucanases are also called endocellulases. Additionally, substitution of one β -glucan degrading enzyme for another would be obvious because both enzymes work on the same fungal molecule.

Art Unit: 1638

Conclusion

16. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

17. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anne R. Kubelik, whose telephone number is (703) 308-5059. The examiner can normally be reached Monday through Friday, 8:30 am - 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson, can be reached at (703) 306-3218. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306 for regular communications and (703) 872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to Customer Service at (703) 308-0198.

Anne R. Kubelik, Ph.D.
March 18, 2003



AMY J. NELSON, PH.D
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600